IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	**NO. 07-348**
MCNEIL-PPC, INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	:	
Defendants.	:	

DuBOIS, J. **January 6, 2012**

M E M O R A N D U M

I. INTRODUCTION

In this products liability action, plaintiff Kiley Wolfe alleges that Children's Motrin manufactured and marketed by defendants caused her to develop Stevens-Johnson Syndrome ("SJS") and Vanishing Bile Duct Syndrome ("VBDS"). Presently before the Court are twenty-one motions in limine: thirteen filed by defendants and eight filed by plaintiff. The Court addresses each motion in turn.

II. BACKGROUND

By Memorandum and Order of March 30, 2011, the Court denied defendants' motion for summary judgment as to plaintiff's failure-to-warn and punitive-damages claims. Wolfe v. McNeil-PPC, Inc., 773 F. Supp. 2d 561 (E.D. Pa. 2011). The Court granted the motion in all

other respects. Id. The factual background of the case is set forth in detail in the Memorandum of March 30, 2011, and will not be repeated in this Memorandum except as is necessary to explain the Court's rulings on the motions in limine.

III. ELEMENTS OF PLAINTIFF'S REMAINING CLAIMS

The Court ruled in its July 30, 2010, Memorandum on choice-of-law issues that Pennsylvania law applies to plaintiff's failure-to-warn claims. Wolfe v. McNeil-PPC, Inc., 703 F. Supp. 2d 487, 491 (E.D. Pa. 2010). To succeed on her claim for negligent failure to warn, plaintiff must meet the standard set forth in section 388 of the Restatement (Second) of Torts. See Overbeck v. Cates, 700 A.2d 970, 972 (Pa. Super. Ct. 1997). That section provides:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
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> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or the facts which make it likely to be dangerous.

To prevail on her strict liability failure-to-warn claim, plaintiff must prove "(1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused the harm." Schindler v. Sofamor, Inc., 774 A.2d 765, 771 (Pa. Super. Ct. 2001) (citation omitted). "A product is defective due to a failure-to-warn where the product was distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the

product." Donoughe v. Lincoln Elec. Co., 936 A.2d 52, 61-62 (Pa. Super. Ct. 2007) (citations omitted).

The Court ruled that Maine law applies to plaintiff's claim for punitive damages. Wolfe, 703 F. Supp. 2d at 493-94. Under Maine law, punitive damages may be awarded only upon a showing that the defendant acted with express or implied "malice." Tuttle v. Raymond, 494 A.2d 1353, 1361 (Me. 1985). Express malice exists where the "defendant's tortious conduct is motivated by ill will toward the plaintiff." Id. Implied malice exists where "deliberate conduct by the defendant, although motivated by something other than ill will toward any particular party, is so outrageous that malice toward a person injured as a result of that conduct can be implied." Id. A defendant's "mere reckless disregard of the circumstances" does not constitute implied malice. Id. Plaintiff must prove by "clear and convincing evidence" that defendant acted with malice. Id. at 1363.

IV. DISCUSSION

A. Motion #1: Adverse Event Reports

Defendants move to exclude evidence of adverse event reports ("AERs") involving ibuprofen and other non-steroidal anti-inflammatory drugs ("NSAIDs") that physicians, patients, and others filed with the Food and Drug Administration ("FDA"). The AERs at issue describe individuals other than plaintiff who may have developed SJS, Toxic Epidermal Necrolysis ("TEN"), or other skin conditions "before or after using ibuprofen . . . or other non-steroidal anti-inflammatory drugs." (Defs.' Mem. Law Supp. Mot. Limine No. 1, at 1.) Defendants assert that the AERs are hearsay, are not substantially similar to the facts of this case, and should be excluded under Federal Rules of Evidence 403 and 703.

The Court grants the motion without prejudice to plaintiff's right to seek reconsideration at trial with respect to particular AERs. With the possible exception of AERs that were sent to the FDA by defendants,[1] defendants are correct that AERs are inadmissible hearsay when offered to prove the truth of the matter asserted: in this case, that a particular drug product is associated with the adverse event the report describes. However, reports submitted to the FDA before plaintiff's alleged injury occurred would not be hearsay if offered on the issue of defendants' notice of potential safety risks from the use of Children's Motrin. See, e.g., Schedin v. Ortho-McNeil-Janssen Pharm., Inc., No. 08-5743, 2011 WL 3837104, at *9 (D. Minn. Aug. 26, 2011) (noting, in a drug product liability case, that the court had previously held AERs admissible on the issue of notice); Hogan v. Novartis Pharm. Corp., No. 06-civ-0260, 2011 WL 1533467, at *13 (E.D.N.Y. Apr. 24, 2011) (admitting AERs on the issue of notice in a drug product liability case); In re Fosamax Prods. Liab. Litig., No. 1:06-MD-1789, 2010 WL 4242708, at *3 (S.D.N.Y. Oct. 27, 2010) (same); Bartlett v. Mutual Pharm. Co., Inc., No. 08-cv-358, 2010 WL 3092649, at *1 (D.N.H. Aug. 2, 2010) (same). However, the Court cannot rule on the admissibility of any specific AER on the issue of notice because, with two exceptions,[2] they have not been submitted to the Court.

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[1]Plaintiff asserts that those AERs that "were sent to the FDA directly by Defendant McNeil" are admissible under Federal Rule of Evidence 803(6) as records of regularly conducted activity. (Pl.'s Answer Opp'n Defs.' Mot. Limine Exclude Evidence Reference Adverse Event Reports 17.) The Court defers ruling on this issue. Plaintiff may attempt to establish at trial that the requirements of Rule 803(6) are satisfied with respect to a particular AER. See Fed. R. Evid. 803(6); see also United States v. Console, 13 F.3d 641, 657-58 (3d Cir. 1993) (requiring that either (1) the person who transmitted the recorded information was under a business duty to provide accurate information, (2) the standard practice was to verify the information provided, or (3) the information transmitted met the requirements of another hearsay exception).

[2]Plaintiff and defendants each attached an "example" AER to their motion papers.

With respect to Rule 403, defendants assert that evidence regarding AERs would be unduly "cumulative and prejudicial" on the issue of notice since they concede that "they were aware of reports of SJS and TEN" prior to plaintiff's alleged injury. (Defs.' Mem. Law Supp. Mot. Limine No. 1, at 15.) The Court rejects this argument. The "persuasive power of the concrete and particular," as opposed to an abstract stipulation, is well recognized. Old Chief v. United States, 519 U.S. 172, 187-89 (1997). If AER evidence presented at trial becomes unduly cumulative, defendants may object at that time. With respect to prejudice, because the parties have submitted only two AERs to the Court, the Court defers ruling on the question whether the probative value of any specific AER is substantially outweighed by the danger of unfair prejudice. In any event, defendants may seek a limiting instruction or other safeguard against any perceived prejudice.

The Court holds further that the substantial similarity doctrine does not bar the admission of AERs reporting SJS or similar illnesses associated with the use of ibuprofen. See, e.g., Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1385-86 (4th Cir. 1995); Bartlett, 2010 WL 3092649, at *1. On this issue, in her response to defendant's motion, plaintiff represents that she will not rely on AERs concerning NSAIDs other than ibuprofen, (see Mem. Law Supp. Pl.'s Answer Opp'n Defs.' Mot. Limine No. 1, at 1), and she will be so limited at trial.

As for the use of AERs as bases for expert testimony, this Court has previously ruled that expert testimony that relies, in part, on case reports to establish causation satisfies the requirements of Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). See Wolfe v. McNeil-PPC, Inc., No. 07-348, 2011 WL 1673805, at *5 (E.D. Pa. May 4, 2011). The Court reiterates its conclusion that, because plaintiff's experts "did not solely rely on case reports in

forming their opinions on causation but used them to supplement their extensive review" of other evidence, such testimony is admissible. Id. As provided in Federal Rule of Evidence 703, where experts in a field would reasonably rely on AERs in forming an opinion, the AERs need not be admissible for the expert opinion to be received in evidence. However, the proponent of the opinion may not disclose the AERs to the jury unless "their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect." Fed. R. Evid. 703. As stated above, the Court does not make such a ruling on the present state of the record.

B. Motion #2: Adverse Drug Reaction Data Listings

Defendants also seek to exclude listings from the World Health Organization's ("WHO's") Adverse Drug Reaction database that contain "ostensible reports" of SJS, TEN, and Erythema Multiforme "allegedly associated with ibuprofen." (Defs.' Mem. Law Supp. Mot. Limine No. 2, at 1.) The issues presented in this motion are nearly identical to those presented with respect to the AERs.

Thus, to the extent plaintiff is able to authenticate the WHO data listings at trial, see Fed. R. Evid. 901(a), the Court adopts its ruling with respect to the AERs. Cf. Bartlett, 2010 WL 3092649, at *1 (treating adverse drug event reports received by the FDA and the WHO identically). Properly authenticated WHO data listings that pre-date plaintiff's alleged injury and involve SJS or similar illnesses associated with the use of ibuprofen may be admissible nonhearsay on the issue of notice. The Court cannot presently rule on the admissibility of any specific WHO data listing, however, as none of them have been submitted to the Court. Unless plaintiff can establish that a particular WHO data listing satisfies the requirements of Rule 803(6), the data listings are not admissible for the truth of the matter asserted. With respect to

Rule 403, the Court defers ruling on the question whether the probative value of any particular WHO data listing is substantially outweighed by the danger of unfair prejudice. If plaintiff fails to authenticate the WHO data listings, they are not admissible for any purpose, subject to the provisions of Federal Rule of Evidence 703. On the present state of the record, this motion is granted without prejudice to plaintiff's right to seek reconsideration at trial with respect to particular documents.

C. Motion #3: Boston University Fever Study Data

Defendants seek to exclude testimony regarding two references to SJS in data from the so-called Boston University Fever Study. (Defs.' Mem. Law Supp. Mot. Limine No. 3, at 1.) Defendant McNeil Consumer Healthcare ("McNeil") sponsored the study, which was conducted between 1991 and 1993, as part of the process of obtaining FDA approval for over-the-counter Children's Motrin. (Id. at 2.) According to defendants, researchers learned through telephone interviews that two study participants had developed SJS either before or after taking ibuprofen. (Id. at 5.)

Defendants anticipate that plaintiff will seek to introduce evidence of those cases to show that (1) ibuprofen causes SJS and (2) defendants failed to report the SJS references to the FDA as AERs and/or in a medical journal article about the study. (Id. at 1.) Defendants argue that the evidence is hearsay, is not relevant, cannot be authenticated, and should be excluded under Rule 403.

The Court grants the motion in part and denies the motion in part without prejudice to the parties' right to seek reconsideration at trial if warranted by changed circumstances, or to object to inadmissible questions. The data would not be inadmissible hearsay if offered on the issue of

defendants' knowledge of the risks of Children's Motrin or alleged misrepresentation to the FDA in failing to report the two SJS cases. The probative value of the data, limited to these issues, is not substantially outweighed by Rule 403 concerns. Cf. Wolfe v. McNeil-PPC, Inc., 773 F. Supp. 2d 561, 575-76 (E.D. Pa. 2011) (stating that evidence of the SJS cases in the study data is relevant to punitive damages). The evidence is not admissible, however, to prove the truth of the matter asserted. It contains two levels of hearsay—it is comprised of statements from parents and patients to study administrators, which the administrators then recorded and passed on to defendants—and plaintiff has not persuaded the Court that any hearsay exception can cure this problem at both levels.

The Court further rules that defendants' production of the documents at issue in this motion sufficiently authenticates those documents. Authentication requires only a "foundation from which a fact-finder could legitimately infer that the evidence is what its proponent claims it to be." In re Japanese Elec. Prods. Antitrust Litig., 723 F.2d 238, 285 (3d Cir. 1985). Production by the opposing party is sufficient to satisfy the requirement. See Bouriez v. Carnegie Mellon Univ., No. 02-2104, 2005 WL 2106582, at *5 (W.D. Pa. Aug. 26, 2005) (citing United States v. Doe, 465 U.S. 605, 614 n.13 (1984)).

D. Motion #4: Evidence that OTC Children's Motrin Label Should Have Contained Warnings Rejected by FDA

Defendants seek to exclude evidence and argument that, when plaintiff was allegedly injured in 1996, the Children's Motrin label should have included warnings mentioning SJS or TEN or otherwise describing the potentially "life-threatening" or serious nature of these conditions. (Defs.' Mem. Law Supp. Mot. Limine No. 4, at 1.) They base this motion on the fact

that a decade after plaintiff became ill, in response to a citizen's petition, the FDA declined to require ibuprofen manufacturers to include that language on their labels. (Id.) Defendants contend that they "cannot be held liable for failing to include warnings that the FDA has already determined should not be used." (Id. at 5.) They thus assert that such evidence or argument is not relevant and should be excluded under Rule 403.

The Court denies this motion. First, in its response to the 2005 citizen's petition, the FDA agreed that the labeling for over-the-counter products "should be improved to warn consumers about the risks of severe skin reactions associated with OTC ibuprofen products." (Id. Ex. A, at 8.) The FDA merely determined that descriptions of symptoms would be more effective than references to the names of illnesses. (Id.)

Second, by way of the changes-being-effected procedure, a drug manufacturer can strengthen its warning label unilaterally when it learns of a new risk posed by its product. Prior to receiving FDA approval for the change, the manufacturer can revise its label to warn of the new risk. See Wyeth v. Levine, 555 U.S. 555, 570 (2009) ("[T]he very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the [changes-being-effected] regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so. . . . [The manufacturer] is charged . . . with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."). That the FDA declined to mandate particular language a decade after plaintiff became ill does not absolve defendants of their responsibility to provide an adequate warning. The Court thus denies defendants' motion on this issue.

E. Motion #5: 2005 Citizen's Petition

Defendants seek to exclude evidence of and reference to the 2005 citizen's petition discussed with respect to the previous motion. (Defs.' Mem. Law Supp. Mot. Limine No. 5, at 1.) The petition warned of the risks of ibuprofen and urged the FDA to take action in response. (Id. at 1-2.) Defendants argue that the petition is hearsay, contains nothing more than claims and arguments, and should be excluded under Rule 403. (Id. at 3-6.)

The Court grants the motion. The petition is hearsay if offered to prove the truth of the matter asserted. Fed. R. Evid. 801(c). Moreover, the Court rejects plaintiff's argument that the petition is admissible on the issue of notice. The petition itself could not have put defendants on notice, as it was filed nearly a decade after plaintiff became ill. The petition catalogs pre-1996 research that might have notified defendants of ibuprofen's risks, but plaintiff can present such information through less prejudicial means than the petition, including expert testimony. Thus, for the purpose of proving notice of the prior research, the petition is subject to exclusion under Rule 403. See Robinson v. McNeil Consumer Healthcare, No. 07-5603 (N.D. Ill. Aug. 12, 2009) (order excluding the citizen's petition on the same grounds).

Plaintiff also seeks a ruling that the FDA's response to the 2005 citizen's petition is admissible. Because that issue has not been fully briefed, the Court does not address it at this time.

F. Motion #6: 1984 Citizen's Petitions

Defendants also seek to exclude evidence of two petitions McNeil submitted to the FDA in 1984.[3] (Defs.' Mem. Law Supp. Mot. Limine No. 6, at 1.) At that time, McNeil manufactured

[3]Both petitions are attached to defendants' motion as exhibits.

acetaminophen but not ibuprofen. (Id. at 2.) In the petitions, McNeil asserted that ibuprofen was dangerous and its OTC warning label should be strengthened. (Id.) Defendants argue that evidence of the petitions is not relevant, should be excluded under Rule 403, and implicates First Amendment concerns embodied by the Noerr-Pennington doctrine.

The Court denies defendants' motion. The petitions are relevant to defendants' knowledge regarding the safety of ibuprofen and the adequacy of its labeling. The facts defendants raise in their motion—for example, the many years that have passed since McNeil submitted the petitions and the changes in circumstances that have occurred during that time—do not render the petitions irrelevant. Defendants may, however, present evidence and argument regarding such facts at trial in an attempt to persuade the jury that the petitions are of little probative value. With respect to the petitions, the Court finds that their probative value is not substantially outweighed by any of the Rule 403 concerns.

Finally, the Court rejects defendants' argument that the Noerr-Pennington doctrine compels the petitions' exclusion. The doctrine applies classically in the antitrust context, where it "provides an 'immunity' from antitrust laws for '[j]oint efforts to influence public officials . . . even though intended to eliminate competition.'" In re Mushroom Direct Purchaser Antitrust Litig., 655 F.3d 158, 165 (3d Cir. 2011) (quoting United Mine Workers v. Pennington, 381 U.S. 657, 670 (1965)).

Aside from the leading cases in this line—Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961), and Pennington—defendants cite a single decision by an intermediate state court to support their assertion. None of the cited cases involve the exclusion of evidence. In the state court case, the court considered (and rejected) an

argument that the First Amendment protected a group of defendants from liability for defamation. See Mann v. Quality Old Time Serv., 15 Cal. Rptr. 3d 215, 225 (Cal. Ct. App. 2004). Defendants' inability to identify a single case in which a court applied Noerr-Pennington to exclude evidence confirms the Court's ruling that the doctrine is inapposite. Cf. In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 789 (7th Cir. 1999) (holding that a district judge "erred in treating the [Noerr-Pennington] doctrine as a rule of evidence").

G. Motion #7: Voluntary Recalls

Defendants seek to exclude evidence of and reference to voluntary recalls McNeil conducted in 2009 and 2010. (Defs.' Mem. Law Supp. Mot. Limine No. 7, at 1.) The recalls involved certain lots of pediatric liquid Motrin and adult and pediatric solid-form Motrin products. (Id.) Defendants aver that the recalls were unrelated to SJS, TEN, or any of plaintiff's claims, (id. at 1-2), and plaintiff does not disagree.

It is defendants' position that the evidence is not relevant and should be excluded under Rule 403. Plaintiff responds that evidence of the recalls, and particularly Congressional testimony relating thereto, is probative of defendant Johnson & Johnson's involvement in the production of Children's Motrin. (Mem. Law Support Pl.'s Answer Opp'n Defs.' Mot. Limine Exclude Evidence Reference McNeil's Voluntary Recalls Certain Products 1-2.) On this issue, the Court notes that Johnson & Johnson has previously stipulated that it "can exercise such authority over McNeil as is available through corporate processes." (Letter of Thomas W. Pulliam, Jr., Doc. No. 125, at 1 n.2.)

The Court grants defendants' motion under Rule 403 because the probative value of the evidence is substantially outweighed by the danger of unfair prejudice its introduction would

create. If the evidence has probative value with respect to Johnson & Johnson's potential liability, such value is extremely limited. The potential prejudice stems from the fact that jurors might be misled into believing similar issues surrounded the Children's Motrin plaintiff allegedly ingested more than a decade before the recalls took place.

H. Motion #8: Foreign Labeling and Regulatory Actions

Defendants seek to preclude plaintiff from introducing any evidence of foreign labeling materials and regulatory actions involving ibuprofen products, asserting that such evidence is not relevant, is hearsay, and should be excluded under Rule 403. (Defs.' Mem. Law Supp. Mot. Limine No. 8, at 1.) Plaintiff contends that, because the labels for some ibuprofen products sold by defendants' affiliates in foreign countries include relatively strong warnings against SJS and related disorders, those labels that pre-date the onset of plaintiff's illness are relevant to show defendants' knowledge of risk. (Mem. Law Supp. Pl.'s Answer Opp'n Defs.' Mot. Limine Exclude Evidence Reference Foreign Labeling Regulatory Actions 3-4.) When offered for that purpose, according to plaintiff, the labels are not hearsay. (Id. at 7.) Moreover, according to plaintiff, the statements are admissible as party admissions under Rule 801(d)(2). (Id. at 8.)

The Court grants defendants' motion without prejudice to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order. The motion seeks to exclude a broad swath of documents that raise diverse evidentiary problems. At trial, if plaintiff wishes to introduce a particular foreign document, the Court will rule on its admissibility as a party admission or on any other ground in the context of the proceedings.

I. Motion #9: "Inadmissible Hearsay Statements Made by FDA Employees"

Defendants move to exclude letters communicating FDA employees' preliminary assessments that certain proposed marketing materials for Motrin were "violative" of FDA regulations. (Defs.' Mem. Law Supp. Mot. Limine No. 9, at 1.) Again, as plaintiff notes, this motion is quite broad. The Court thus grants the motion without prejudice to plaintiff's right to seek reconsideration with respect to specific documents at trial.

J. Motion #10: Marketing and Promotional Materials Not Relied upon by Plaintiff or Her Family

Defendants seek to exclude evidence of Children's Motrin marketing materials on which plaintiff and her family did not rely. Defendants argue that such evidence is irrelevant and should be excluded under Federal Rule of Evidence 403. (Defs.' Mem. Law. Supp. Mot. Limine No. 10, at 1.) Plaintiff responds that (1) defendants' extensive marketing efforts show defendants could have afforded to put more money into safety, (2) the marketing materials show Johnson & Johnson "endorsed" McNeil's representations about Motrin, and (3) such evidence is probative of malice, which could justify punitive damages. (Pl.'s Mem. Law Opp'n Defs.' Mot. Limine No. 10, at 5-6.)

The Court grants defendants' motion without prejudice to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order. Plaintiff's relevance arguments are weak, and, under Rule 403, a substantial risk of unfair prejudice outweighs that limited relevance. The jury might wrongly presume plaintiff saw the advertisements at issue or might focus on the sufficiency of defendants' overall marketing, even though the Court granted defendants' motion for summary judgment as

to plaintiff's negligent-marketing claim. See Wolfe, 773 F. Supp. 2d at 570-71.

K. Motion #11: Other Lawsuits, Claims, or Settlements

Defendants move to "preclude [p]laintiff from presenting evidence of or making references to lawsuits, claims or settlements regarding non-parties who allegedly experienced adverse reactions from ingesting Children's Motrin and/or other ibuprofen products." (Defs.' Mem. Law Supp. Mot. Limine No. 11, at 1.) Defendants do not identify the particular lawsuits, claims, or settlements to which they refer, but they argue that such evidence is irrelevant, hearsay, inadmissible character evidence, and subject to exclusion under Rule 403. Plaintiff asserts that the evidence is admissible on the issue of defendants' notice of the hazards of Children's Motrin.

The Court grants this motion without prejudice to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order. Evidence of lawsuits, claims, or settlements that pre-date plaintiff's ingestion of Children's Motrin may be relevant to the issue of notice, but the Court cannot so rule on the present state of the record.

Plaintiff also refers to "standby statements" defendant McNeil produced and then changed after it was sued. (Pl.'s Mem. Law Opp'n Defs.' Mot. Limine No. 11, at 6.) As the parties have not provided the Court with any examples of these documents, plaintiff must seek the Court's prior approval before mentioning other lawsuits, claims, or settlements in connection with them in the presence of the jury. On the present state of the record, subject to reconsideration at trial, all evidence of lawsuits, claims, and settlements involving non-parties who allegedly experienced adverse reactions after ingesting ibuprofen products is inadmissible.

L. Motion #12: Rechallenges in Upjohn Clinical Trials

Defendants seek to exclude evidence that in clinical studies conducted by Upjohn, another pharmaceutical company, some individuals who had previously experienced an "adverse event" developed SJS and related disorders after repeated administration of ibuprofen. Defendants anticipate that plaintiff will attempt to establish this through expert testimony, but according to defendants, plaintiff's experts have not yet identified the clinical studies to which they refer. Plaintiff attaches exhibits to her response that, while difficult to decipher, purport to be the relevant data from the Upjohn trials. Upjohn allegedly conducted the studies prior to plaintiff's ingestion of Children's Motrin and the onset of plaintiff's illness. (See Defs.' Mem. Law Supp. Mot. Limine No. 12, at 2.)

Because the parties' submissions do not fully explain the nature of the documents at issue—or the sufficiency of their pretrial disclosure—the Court grants the motion without prejudice to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order. Plaintiff must lay a foundation for the documents before seeking to introduce them at trial. If plaintiff does so, references to SJS in the Upjohn data made known to defendants prior to plaintiff's illness may be admissible on the issues of notice and defendants' alleged insufficient reporting to the FDA. See Fed. R. Evid. 801(c). The SJS references are not admissible for the truth of the matter asserted.

M. Motion #13: Drugs Withdrawn or Removed from the Market

Defendants' final motion seeks to exclude evidence of the market withdrawal of drugs other than Motrin. (Defs.' Mem. Law Supp. Mot. Limine No. 13, at 1.) Defendants assert that evidence of the withdrawals is irrelevant and subject to exclusion under Rule 403 because the

withdrawn drugs have different manufacturers and safety profiles and are alleged to have caused different injuries than those at issue here. (Id.)

In her response to the motion, plaintiff states that she will refer only to the withdrawal of ibuprofen products and other NSAIDs based on their possible connection to SJS and related disorders. (Pl.'s Mem. Law Opp'n Defs.' Mot. Limine No. 13, at 1.) Such withdrawals might be relevant to general causation—the question of whether defendants' product can, in general, cause the type of injuries of which plaintiff complains—but the Court cannot so rule on the present state of the record. Thus, this motion is granted without prejudice to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order.

N. Motion #14: Evidence that Anyone Other than a Drug Manufacturer Has Ultimate Responsibility for Providing Adequate Warning Labels

Plaintiff seeks to preclude defendants "from presenting evidence, reference, argument, suggestion and/or innuendo that anyone other than a drug manufacturer [such as the FDA] has the ultimate responsibility for providing adequate warning labels." (Mem. Law Supp. Pl.'s Mot. Limine Exclude Any Evidence, Reference, Argument, Suggestion, Innuendo Anyone Other Than Drug Manufacturer Has Ultimate Responsibility Providing Adequate Warning Labels 1.) Plaintiff relies on the Supreme Court's opinion in Wyeth v. Levine, 555 U.S. 555, 570 (2009), in which the Court rejected an argument that "the FDA, rather than [a drug] manufacturer, bears primary responsibility for drug labeling." The Court held that "a central premise of federal drug regulation" is that a "manufacturer bears responsibility for the content of its label at all times." Id. at 570-71.

Defendants do not deny this proposition. Because the evidence and argument plaintiff seeks to exclude are inadmissible or otherwise improper, the Court grants this motion. This does not preclude defendants, however, from presenting evidence regarding the scope of the FDA's authority and the regulatory framework within which defendants and other pharmaceutical companies operate.

O. Motion #15: Evidence that Compliance with FDA Regulations Absolves Defendants of Liability

Again relying on Wyeth, plaintiff seeks to preclude defendants "from presenting evidence, reference, argument, suggestion and/or innuendo that compliance with FDA regulations absolve [sic] [d]efendants of liability as a matter of law." (Mem. Law Supp. Pl.'s Mot. Limine Exclude Any Evidence, Reference, Argument, Suggestion, Innuendo Compliance FDA Regulations Absolve Defs. Liability Matter Law 1.) Defendants stated in their response to the motion that they will not make such argument at trial. Because the evidence and argument plaintiff seeks to exclude are inadmissible or otherwise improper, the Court grants this motion. Again, however, defendants may explain the regulatory framework and their compliance with applicable regulations.

P. Motion #16: Evidence that Manufacturer Could Not Change Warning Label Without Prior FDA Approval

Plaintiff seeks to preclude defendants from suggesting that a manufacturer must obtain approval from the FDA before changing the warning label on a pharmaceutical product. (Mem. Law Support Pl.'s Mot. Limine Exclude Any Evidence, Reference, Argument, Suggestion, Innuendo Drug Manufacturer Could Not Change Warning Label Medication Without Prior FDA Approval 1.) Plaintiff relies on language in Wyeth and on the availability of the changes-being-

effected procedure. (Id. at 1-4.)

Defendants stated in their response that they will not "argue that manufacturers can never change their warning labels without prior approval, or otherwise raise legal preemption as a factual defense at trial." (Defs.' Resp. Pl.'s Mot. Limine Exclude Any Evidence, Reference, Argument, Suggestion, Innuendo Drug Manufacturer Could Not Change Warning Label Medication Without Prior FDA Approval 1.) Because the evidence and argument plaintiff seeks to exclude are inadmissible or otherwise improper, the Court grants this motion. Defendants may, however, offer evidence regarding the regulatory framework and their decision not to use the changes-being-effected procedure.

Q. Motion #17: FDA Preamble

Plaintiff seeks to exclude evidence of or reference to a so-called "FDA preamble" regarding the regulation of OTC drugs. (Mem. Law Supp. Pl.'s Mot. Limine Exclude Any Evidence Reference Current FDA Preamble 1.) The FDA promulgated regulations in 2006 and 2008 stating that it "interprets the [Federal Food, Drug, and Cosmetic Act] to establish both a 'floor' and a 'ceiling'" on the regulation of drug labeling. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2850 n.3 (Jan. 16, 2008); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934-35 (Jan. 24, 2006). The Supreme Court wrote in Wyeth that the preamble appeared to be inconsistent with legislative intent and was "inherently suspect" due to procedural defects in its passage. Wyeth, 555 U.S. at 577-78. Defendants stated in their response that they will not refer to the preamble language without the Court's prior approval. The Court thus grants plaintiff's motion.

R. Motion #18: Evidence that Plaintiff's Mother Takes Ibuprofen or Gives It to Her Other Children

Plaintiff seeks to exclude evidence that plaintiff's mother uses ibuprofen or gives it to her other children, arguing that such evidence is not relevant to any issue in this case. (Pl.'s Mem. Law Support Mot. Limine Exclude Any Evidence, Reference, Argument, Suggestion, Innuendo Pl.'s Mother Uses Ibuprofen Gives It Her Other Children 1.)

The Court denies this motion. Evidence that plaintiff's mother uses ibuprofen despite a strengthened warning label is relevant to causation, which is an "essential element" of a failure-to-warn claim. Simon v. Wyeth Pharm., Inc., 989 A.2d 356, 358 (Pa. Super. Ct. 2009). "[T]he plaintiff must establish that it was the total lack or insufficiency of a warning that was both a cause-in-fact and the proximate cause of the injuries." Pavlik v. Lane Ltd./Tobacco Exps. Int'l, 135 F.3d 876, 881 (3d Cir. 1998). As this Court stated in its Memorandum of March 30, 2011, evidence that plaintiff's mother continues to use ibuprofen products, despite their strengthened warning label, has some bearing on whether she would have given plaintiff Children's Motrin even if defendant had provided a stronger warning. See Wolfe, 773 F. Supp. 2d at 570 ("Leland's testimony that she still takes ibuprofen products . . . may bear on the jury's assessment of whether she would have heeded a stronger warning . . . ."). Plaintiff may attempt to persuade the jury otherwise through cross-examination and presentation of her own evidence.

S. Motion #19: Preclude Johnson & Johnson from Denying It Manufactures, Markets, Distributes, and Sells Children's Motrin

Plaintiff seeks to preclude defendant Johnson & Johnson from implying that it cannot be held liable in this case because it does not manufacture, market, or sell Children's Motrin. Plaintiff relies mainly on Congressional testimony in which Johnson & Johnson executives

implied an ability to exercise some control over McNeil. (See Pl.'s Mem. Supp. Mot. Limine Preclude Def. Johnson & Johnson Denying It Manufactures, Markets, Distributes, Sells Children's Motrin.) Johnson & Johnson has previously stipulated that it "can exercise such authority over McNeil as is available through corporate processes." (Letter of Thomas W. Pulliam, Jr., Doc. No. 125, at 1 n.2.)

The Court denies plaintiff's motion. Defendants must abide by their stipulation, but plaintiff has the burden of establishing alter ego liability. Neither the stipulation nor the Congressional testimony does so conclusively.

T. Motion #20: Evidence that Plaintiff Did Not Have SJS

Plaintiff moves to preclude defendants from arguing that plaintiff did not have SJS. Plaintiff argues that such evidence should be excluded under Rules 403 and 703 "because there is no factual foundation in the record which would support such argument or innuendo, and any arguments to the contrary would only confuse and mislead the trier of fact." (Mem. Law Supp. Pl.'s Mot. Limine Exclude Any Evidence, Reference, Argument, Suggestion, Innuendo Kiley Wolfe Did Not Have Stevens-Johnson Syndrome 4).

Plaintiff's motion is denied. The Court has already held that expert testimony that plaintiff may not have had SJS is admissible under Daubert. See Wolfe, 2011 WL 1673805, at *14-16. Moreover, evidence that plaintiff did not have SJS is highly relevant. To cast doubt on whether plaintiff became ill with SJS is also to cast doubt on whether defendants' product caused plaintiff's alleged injury. Such evidence will not confuse the jury or otherwise cause unfair prejudice. Plaintiff may use cross-examination and her own evidence to discredit argument or evidence that she did not have SJS.

U. Motion #21: Evidence that Plaintiff Took Aleve

Plaintiff seeks to exclude evidence that she took a dose of Aleve to treat a headache two days before she began the course of Children's Motrin that allegedly caused her illness. (Pl.'s Mem. Law Supp. Mot. Limine Exclude Any Evidence, Reference, Testimony Kiley Wolfe Took Aleve 1.) She argues that such evidence is irrelevant to the issues of causation and defendants' failure to warn and emphasizes that none of defendants' experts have opined that Aleve caused her injuries. (Id. at 2-3.)

The Court denies this motion. Evidence that plaintiff took Aleve shortly before she took Children's Motrin is relevant to issues in this case. First, it could create doubt as to what caused plaintiff's alleged illness. There is some evidence that naproxen, the active ingredient in Aleve, may be associated with SJS and related disorders. See AHFS Drug Information § 28:08.04.92 (2008). Second, as this Court stated in its March 30, 2011, Memorandum, plaintiff's mother's "admission that she gave her daughter an Aleve from a stranger without reading the label . . . may bear on the jury's assessment of whether she would have heeded a stronger warning."[4] Wolfe, 773 F. Supp. 2d at 570.

V. CONCLUSION

For the foregoing reasons, using the numbering contained in this Memorandum's headings, the following motions are denied: Motion #4, Motion #6, Motion #18, Motion #19, Motion #20, and Motion #21. The following motions are granted: Motion #5, Motion #7, Motion #14, Motion #15, Motion #16, and Motion #17. The following motions are granted without

[4]The Court need not decide at this point whether plaintiff is entitled to a heeding presumption. Even if such a presumption applies, defendants are entitled to present evidence to rebut it. See Pavlik, 135 F.3d at 883 (noting that the heeding presumption is rebuttable).

prejudice: Motion #1, Motion #2, Motion #8, Motion #9, Motion #10, Motion #11, Motion #12, and Motion #13. Motion #3 is granted in part and denied in part without prejudice.

The Court states in its Memorandum with respect to some rulings that the aggrieved party or parties may seek reconsideration if warranted by changed circumstances or evidence adduced at trial. Notwithstanding that limitation, any aggrieved party may seek reconsideration of the rulings in this Memorandum. An appropriate Order follows.